

Autism Research Institute

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Mark McClellan, M.D., Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

(by Fed Ex)

Dear Dr. McClellan,

Subject: FDA regulations concerning autism.

As parents of adult autistic sons, and as professional scientists who have dedicated decades of our lives to research on the cause and treatment of autism, we wish to express our profound disagreement with the FDA's statements and policies regarding autism, which appear on the FDA website:

FDA's enforcement efforts to date have covered a wide array of supplement products. Based on its experience in this area, the agency has identified certain products that are clearly problematic and which warrant close scrutiny. They include the following:

- ° Autism Treatments: Parents of autistic children can be desperate and provide easy targets for unproven therapies. Marketers of dietary supplements for autistic children contend that their products promote more complete food digestion, thereby preventing neurotoxic molecules that contribute to autism. This is a false and unsupported claim.

- ° Treatments for Behavioral Disorders: Like parents of autistic children, parents of children with behavioral disorders (e.g., Hyperactivity and Attention Deficit Disorder) are vulnerable targets for sham products. These parents want their children to behave normally and want to avoid "drugging" them. Supplements claiming to treat these disorders promise time-tested methods that offer an alternative to drug therapy. These products often claim to contain ingredients that respond to the neurochemical bases of the behavioral problem. In fact, the physiological causes of these disorders are not fully understood and these claims are patently false.

The concerns expressed above about the efficacy of treatments for autism are grossly exaggerated. Recent developments strongly contradict the unjustifiably pessimistic view of your agency.

Was there a call for public input prior to the issuance of the above policies? If so, we and the scores of physicians and scientists with whom we collaborate were not aware of such a notice or call for public input.

There is a great deal of compelling evidence, from many sources, that a large percentage of autistic children can improve markedly, and some may in fact recover, when provided with the dietary treatments and

nutritional supplements that are cavalierly dismissed by your agency's policy statement. Abstracts of 55 articles on the topic of dietary intervention in autism may be found at www.autismNDI.com/studies.

The value of certain nutritional supplements is also well established in the literature. A series of 22 studies, including 11 double-blind-placebo crossover studies, have demonstrated the value of high dosage vitamin B6 and magnesium in the treatment of autism. (website address: www.autism.com/B6Studies) .

We are able to present well-documented testimony from scores of physicians demonstrating the value of diet and supplements in bringing about marked improvement in hundreds of autistic children – many of whom are the children of these physicians. Initially, these physicians were almost uniformly skeptical about the approaches we advocate. They investigated our interventions as a last resort, because the conventional treatment approaches, based primarily on prescription drugs, were of marginal benefit and conferred considerable risk.

We note with astonishment and chagrin the FDA's statement that the use of supplements may be summarily dismissed on the nonsensical grounds that "the physiological causes of these [behavioral] disorders are not fully understood and these claims are patently false." Aspirin, quinine, lime juice, and a multitude of other natural substances were used effectively to treat pain, malaria and scurvy etc. for many decades on a strictly empirical basis, even though "the physiological causes of these disorders were not understood." To assert, as the FDA's statement does, that "these claims are patently false" is absurd. We cannot in good conscience acquiesce to the FDA's enforcement of policies which are based on lack of awareness of the scientific and empirical clinical evidence that contradict the premises of the policies. Nor can we accept the obviously unsupportable position that remedies for which the physiological bases are not fully understood must be worthless. The lives and the well-being of tens of thousands of autistic children throughout this country are far too important, to us and to their parents, as well as to society, to permit implementation of your agency's policies without due process.

The FDA's pejorative comments on special diets and nutritional supplements as treatments for autism cannot be justified by claiming that these approaches divert parents from proven and approved treatments. There are none. Most of the drugs, such as risperidone, which are the mainstay of the majority of conventional practitioners, have not been approved for use with children and carry significant risk of serious side effects, including death. The PDR listings of these drugs commonly state that their physiological effects are not understood. What is the logic in disapproving harmless treatments whose physiological bases are not perfectly understood so the children can then be treated with drugs, similarly not perfectly understood, with potentially fatal consequences?

Our position is based not only on our ongoing monitoring of the medical literature and the clinical experiences of hundreds of physicians, but on our ongoing collection of parent ratings of the safety and efficacy of drugs, diets and supplements (N = 22,500 responses to date).

We respectfully request that the FDA rescind the unsubstantiated statements cited above, and abstain from enforcing the policies which flow from these statements until we, and our colleagues, as well as other members of the public, have had an opportunity to present the information your agency has ignored.

Judging from what we have read about you, you are a reasonable and fair-minded person. We invite you to attend our forthcoming Defeat Autism Now! (DAN!) conference which will be held in Philadelphia May 16-18th. We would welcome an opportunity to discuss these matters with you at our conference, or perhaps we could visit you at your office.

We enclose a copy of the DAN! Conference brochure, which, as you will note, stresses the gains our group has made in recent years in understanding the physiological basis of autism and its treatment. The current thrust of DAN! is to elucidate and connect all of the nucleotide/nucleoside metabolism disorders with symptoms that are also typically seen in autism. There are at least a dozen such conditions with known and understood genetic and molecular problems. One of our major objectives is to determine how diet and nutritional supplements can favorably influence these conditions.

Please note that the Pediatric Gastroenterology Department of the Harvard Medical School/Massachusetts General Childrens Hospital has embarked on a five-year multicenter project designed to evaluate the treatment approach that has evolved from the DAN! efforts.

Tim Buie, M.D., of the Harvard Pediatric Gastroenterology team, which has studied 800 autistic patients, has confirmed a finding which has been recorded very frequently: laboratory tests consistently show abnormal levels of minerals, essential fatty acids and amino acids, probably caused by poor absorption, metabolic errors, or self-limited diets. Many autistic children show remarkable improvement when these problems are mitigated through dietary changes and/or supplements. It is not claimed that giving the supplements, or changing the diet, cures autism, but it brings about improvement in the child's well being and behavior as a result of correcting the nutritional deficiencies, whatever the cause of these deficiencies may be.

Dr. Buie points out that some years ago children with sickle cell anemia also presented with a great many physical problems and abnormal clinical lab test findings, which were thought to be the consequence of the sickle cell gene. Nevertheless, correcting the nutritional deficiencies brought about highly significant improvement in these children, without changing the genetic problem which in some way was the underlying cause of the child's poor nutritional status. The situation with autism is, of course, highly analogous.

This is a very urgent matter. The unduly pessimistic position by the FDA will be a self fulfilling prophesy which will condemn many thousands of autistic children and their families to nightmarish consequences.

We hope to hear from you soon.

Sincerely,

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